

REMARKS

The rejection of the claims under 35 USC §102(b) and 103 has been obviated by amending the claims to more clearly define the invention over the art of record. Specifically, amended claim 1 now recites a sterilization bag characterized in that side edges and lower ends of a gas-permeable material and a synthetic resin film are adhered with an opening remaining in an upper end thereof, and further comprising a damage prevention means that prevents damage of at least one selected from the gas-permeable material, and an adhered portion of the gas-permeable material and the synthetic resin film by catching or receiving the tips of stored articles in the lower end portion of the sterilization bag or vicinity thereof,

wherein the damage prevention means is a protective sheet material disposed in the inner surface of only the lower end portion of the sterilization bag, the protective sheet material being fixed to at least the gas permeable material, wherein the damage prevention means prevents damage by catching the tip of stored articles.

None of the references of record either discloses or suggests the sterile bag defined in amended claim 1. All that the newly cited Weiss '489 patent discloses is a sterilizable flexible pouch package having a perforated, intermediate web 12 sandwiched between a lower, steam permeable web 11 and upper web 13. As set forth in column 6, lines 52-56, the purpose of the intermediate web 12 is to strengthen the pouch so that heavy objects contained therein may be sterilized:

One of the principal advantages of the invention is in the ability to use the pouch for steam sterilizing heavy objects weighing up to about thirty pounds. Lower web 11 together with intermediate web 12 will support the weight of an object in the pouch. If web 12 is sufficiently strong to bear the entire load, the load-bearing strength of web 11 is not of particular concern. Quite the opposite is true, of course, if web 12 has little load bearing strength.

The heat seals 14, 15 between the sides of the lower and upper webs 11 and 13 are **not** made **directly** between the lower and upper webs 11, 13. Instead, the Weiss '489 patent teaches making these heat seals 14, 15 **through the intermediate web 12**. Weiss further teaches

making the intermediate web 12 from a laminate of different plastic materials that are well suited to thermally bond with the particular webs 11, 13 that they contact, as set forth on column 7, lines 39-52:

Intermediate web 12 is a flexible heat sealable plastic web having a bottom layer 121, a core layer 122, and a top layer 123. The terms "top" and "bottom" are again used in a sense of the normal orientation of the pouch in use, that is, with the pouch disposed generally horizontally with upper web 13 uppermost as shown in FIGS. 2 and 3. Top layer 123 of web 12 is a plastic layer which forms a hermetic permanent line heat seal 15 with upper web 13, and is preferably polypropylene or a polypropylene copolymer such as a propylene-ethylene copolymer, or blends thereof. Preferred propylene-ethylene copolymers contain ethylene in the range of up to 6%, preferably 1-5%. Bottom layer 121 of web 12 is a plastic which forms a hermetic permanent line heat seal 14 with barrier web 11.

Because the intermediate web 12 must extend across the **entire length** of the pouch to effect the side heat seals 14 and 15, the Weiss '489 patent teaches against the recited "protective sheet material disposed in the inner surface of only the lower end portion of the sterilization bag,..." Accordingly, amended claim 1 is clearly patentable over the Weiss '489 patent.

As pointed out before, all that the Ota '518 Japanese patent document discloses is a bag for sterilization having opposing sides comprising a side front film 11 and a gas permeable sheet 12, and a bottom film 10 that is folded and heat sealed along its side edges 13 to the side edges of the film 11 and sheet 12 to form a boat-shaped bottom (see Figures 2, 4 and 6, and paragraph [0021]). There is no damage-preventing component or structure whatever at the boat-shaped bottom; hence the adhesive joints between the gas permeable sheet 12 and the bottom film 10 are vulnerable to being de-laminated by the tips of surgical instruments stored in the bag, particularly when the bag is oriented into an upright position. Accordingly this reference neither discloses nor suggests a "protective sheet material disposed in the inner surface of only a lower end portion of the sterilization bag,..." For this reason alone, amended claim 1 is clearly patentable over the Ota '518 patent.

Nor is amended claim 1 rendered "obvious" by any tenable combination of the Weiss '489 and Ota '518 patents. In view of the aforementioned teachings of the Weiss '489 patent, any combination of the Weiss '489 and Ota '518 patents would result in the pouch of Ota with an intermediate web sandwiched **the entire length** of the front side film 11 and the

paper sheet 12, as such a structure would be necessary to effect the side heat seals 14 and 15 disclosed in the Weiss '489 patent. The resulting structure would clearly **not** have the claimed "protective sheet material disposed in the inner surface of only a lower end portion of the sterilization bag, ..." Hence, amended claim 1 is clearly patentable over any combination of the Weiss '489 and Ota '518 patents.

Claims 2-7 have been cancelled, and hence no further discussion is deemed necessary.

Claims 8 and 9 are patentable at least by reason of their ultimate dependency on amended claim 1.

Claim 10 is patentable not only for its dependency on amended claim 1, but for its recitation that "the protective component is a bag component formed by mountain folding a third synthetic resin film", another feature neither disclosed nor suggested by the prior art of record.

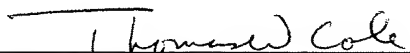
Finally, claims 11 and 12 are patentable at least by reason of their dependency on amended claim 1.

Now that all of the claims are believed to be allowable, the prompt issuance of a Notice of Allowability is hereby earnestly solicited.

As the aforementioned amendments do not present any substantial new issues in the prosecution of this case, applicant respectfully request the Examiner to enter this amendment and to allow this case without the need for the filing of an RCE.

Respectfully submitted,

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Thomas W. Cole
Registration No. 28,290

Customer No. 25570

Roberts Mlotkowski Safran & Cole, P.C.
P.O. Box 10064
McLean, VA 22102
Telephone: (703) 677-3001